EXHIBIT 11

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF TEXAS SHERMAN DIVISION

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Plaintiff,

V.

ST. JUDE MEDICAL S.C., INC., et al.,

Defendants.

CIVIL ACTION NO. 4:16-cv-812

JURY TRIAL DEMANDED

MOTION TO EXCLUDE CERTAIN OPINIONS
OF DR. YOGANATHAN AND DR. BROWN

Table of Contents

I.	DR. Y	YOGANATHAN'S PRACTICING-THE-PRIOR-ART OPINIONS	1
II.	DR. Y	YOGANATHAN'S ENABLEMENT OPINIONS	2
	A.	Dr. Snyders Was Not Required To Enable the Accused Device	3
	B.	Dr. Snyders' Valve "Works" In The Sense Required By Enablement	3
III.	DR. Y	OGANATHAN'S RELIANCE ON SJM'S INVALIDITY CONTENTIONS	6
IV.	DR. Y	OGANATHAN'S OPINIONS ON UNDISCLOSED THEORIES	7
V.	DR. E	BROWN'S WRITTEN-DESCRIPTION OPINIONS	8
VI.	CON	CLUSION	11

I. DR. YOGANATHAN'S PRACTICING-THE-PRIOR-ART OPINIONS

Dr. Yoganathan opines that various claim elements are met by the prior art under Snyders' infringement positions, even though he expressly disagrees with those positions. Here are some examples:

- "Although I disagree, If Snyders's position is correct, then Leonhardt teaches the claim limitations reciting "peripheral anchor(s)," and "anchors" to the same extent." Ex. 1 at ¶ 320 [Excerpts1—Yoganathan Report] (emphasis added).
- "*To the extent* that Snyders is relying on radial or outward force of a frame as being the claimed 'peripheral anchors(s)' or the claimed 'anchor,' then these disclosures from Andersen show that Andersen teaches these limitations *to the same extent as Portico*." *Id.* at ¶ 328 (emphasis added).
- "Andersen also teaches a 'central portion' and 'central portion located between the plurality of anchors' *according to Snyders's interpretation of these claim elements*." *Id.* at ¶ 352 (emphasis added).
- "I do not agree. However, if Snyders' position is correct, then Bessler at the very least teaches '782 patent claim limitation 10(c)" Id. at ¶ 385 (emphasis added).
- "Andersen teaches a plurality of peripheral anchors *under Snyders's infringement position.*" *Id.* at ¶ 424.

These examples are by no means exhaustive. *See id.* at ¶¶ 320-22, 325-28, 331, 334-52, 357, 358, 361, 362, 365, 366, 369, 370, 378, 379, 384, 385, 391, 397, 403, 407, 408, 414, 415, 418, 419, 423, 424, 428, 430, 434, 440-43, 448, 450-56, 459-61, 463-65, 469-74, 481-86, 493-512, 522-26, 530, 532, 534, 536, 551 n.3. Additionally, Dr. Yoganathan's report includes a section that is expressly devoted to comparing the prior art to the accused Portico products, rather than to the claims of the patents-in-suit. *See id.* at ¶¶ 213-216.

The Court should exclude these paragraphs because they assert an improper "practicing the prior art" defense. *See, e.g., Zenith Elecs. Corp. v. PDI Comm'n Sys., Inc.*, 522 F.3d 1348, 1363-64 (Fed. Cir. 2008); *Tate Access Floors, Inc. v. Interface Architectural Resources, Inc.*,

279 F.3d 1357, 1363 (Fed. Cir. 2002); Ex. 2 at 5-6 [Core Wireless Licensing S.A.R.L. v. LG Electronics, Inc., Case No. 2:14-cv-912-JRG-RSP (E.D.Tex. July 12, 2016)]; Metaswitch Networks Ltd. v. Genband US LLC, 2016 WL 3618831 *8-9 (E.D. Tex. March 1, 2016).

II. DR. YOGANATHAN'S ENABLEMENT OPINIONS

The Court should exclude Dr. Yoganathan's opinions on enablement because he applies an incorrect legal standard and he relies on legally insufficient facts. *See, e.g., Apple, Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1314 (Fed. Cir. 2014) ("[A] district court judge, acting as a gatekeeper, may exclude evidence if it is based on unreliable principles or methods, or *legally insufficient* facts and data.") (emphasis added); *Personalized Media Comm., LLC v. Zynga, Inc.*, Case No. 212-cv-68-JRG-RSP, 2013 WL 5962812, *2 (E.D. Tex. Nov. 7, 2013) (excluding enablement opinions under Rules 702 and 403 as methodologically flawed and likely to be misleading to the jury); *Inline Connection Corp. v. AOL Time Warner Inc.*, Case No. 02-272MPT, 2007 WL 275928, at *5 (D. Del. Jan. 29, 2007) ("Because Wang did not conduct a proper enablement analysis, his opinion is not reliable and is not admissible on enablement.").

Section 112, paragraph 1 requires that a patent specification enable "those skilled in the art to make and use the full scope of the claimed invention without undue experimentation." *Koito Mfg. Co., Ltd. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1155 (Fed. Cir. 2004). But that does not mean that every embodiment must be enabled. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1335 (Fed. Cir. 2003) ("[T]he law makes clear that the specification need teach only one mode of making and using a claimed composition."). Moreover, "a patent applicant does not need to include in the specification that which is already known to and available to one of ordinary skill in the art." *Id.* at 1156; *see also In re Gay*, 309 F.2d 769, 774 (C.C.P.A. 1962) ("Not every last detail is to be described, else patent specifications would turn

into production specifications, which they were never intended to be.").

Dr. Yoganathan has two opinions regarding enablement. Both are legally untenable.

A. Dr. Snyders Was Not Required To Enable the Accused Device

Dr. Yoganathan posits that, to the extent Snyders asserts that its claims cover the accused Portico device's features, that embodiment is not disclosed and thus the claims are not fully enabled. *See* Ex. 3 at 58-66 [Excerpts2—Yoganathan Report]. This argument is legally erroneous because it compares the patent disclosures to the accused device, rather than the claims. *Durel Corp. v. Osram Sylvania Inc.*, 256 F.3d 1298, 1306 (Fed. Cir. 2001) ("The dispositive question of enablement does not turn on whether the accused product is enabled."); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1335 (Fed. Cir. 2003) ("[T]he law makes clear that the specification need teach only one mode of making and using a claimed composition. This conclusion again makes the specification's failure to disclose [the accused infringer's accused technology] legally irrelevant." (internal quotations omitted)); *see also Personalized Media Comms., LLC v. Zynga, Inc.*, No. 2:12-cv-00068-JRG-RSP, 2013 WL 5962812, at *2 (E.D. Tex. Nov. 7, 2013) (striking defendant's expert's opinion that claims were not enabled because specification did not teach how to make the accused product).

B. Dr. Snyders' Valve "Works" In The Sense Required By Enablement

Dr. Yoganathan also opines that the claims are not enabled because the disclosed embodiments do not work. Dr. Yoganathan opines that the only embodiments disclosed by the 782 Patent each have four-attachment points. *See* Ex. 3 at ¶¶130-33, 138 [Excerpts2—Yoganathan Report]. Dr. Yoganathan then opines that the Dr. Snyders testified that such an embodiment would not work. *See, e.g., id.* at -134-37.

Dr. Yoganathan ignores the 3-attachment point embodiment disclosed in Dr. Snyders'

provisional application, which the 782 Patent incorporates by reference. *See, e.g.,* Ex. 4 at B-9 [Prov. App]. Dr. Yoganathan concedes that Figure 3 of the '297 patent depicts a three-attachment-point valve. He does not contend that this three-attachment point embodiment would not work. Dr. Yoganathan nonetheless opines that, because the patent claims also encompass an allegedly non-enabled four-attachment-point valve, they are invalid. That is incorrect. Even assuming that the disclosed four-attachment-point valve is not enabled, that the claims are broad enough to cover non-enabled embodiments would not render them invalid. *Johns Hopkins University v. CellPro, Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998) (affirming grant of summary judgment on enablement).

Even if Dr. Yoganathan had been correct that the 782 Patent discloses only a four-attachment embodiment, his enablement opinions would still be legally untenable. Dr. Yoganathan opines that Dr. Snyders' testimony establishes that the four-attachment-point valve does not enable the claim preambles' "repairing a damaged heart valve" term. But Dr. Snyders did not testify—and there is no other evidence—that the four-attachment-point valve would not work to "repair a damaged heart valve." Instead, Dr. Snyders testified—and Dr. Yoganathan agreed—that, due to geometrical constraints, the four-attachment-point valve would not *open fully to the midline*. Ex. 5 at 181:3-8 [Snyders Depo] ("That would not work. . . . You can't have one-fourth a circumference *reaching its midpoint to the point of occlusion*." (emphasis added)); *see also* Ex. 3 at ¶ 136 [Excerpts2—Yoganathan Report]. The claims, however, do not require opening fully to the midline. And there is no evidence that a valve that does not open fully to the midpoint would not, nonetheless, work to "repair[] a damaged heart valve." Because Dr. Yoganathan's opinion does not tie Dr. Snyders' testimony to the claims, it does not provide an admissible opinion on enablement under the correct legal standard. *See Ortho-McNeil*

Pharm. Inc. v. Mylan Labs. Inc., Nos. 04-1689, 06-757, 2006 WL 2865469, at *4-5 (D.N.J. Oct. 5, 2006) (granting partial summary judgment in favor of patentee on enablement defense).

Dr. Yoganathan's opinion attempts to "set the enablement bar too high." *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1338 (Fed. Cir. 2003). Whereas a valve that opens fully to the midline may have been desirable, even optimal, in a commercial embodiment, "[e]nablement does not require an inventor to meet lofty standards for success in the commercial marketplace," nor does it "require that a patent disclosure enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect." *Id.; see also Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.*, 617 F.3d 1296, 1307 (Fed. Cir. 2010) (holding that a specification "is not required to enable the most optimized configuration, unless this is an explicit part of the claims.").

Moreover, even assuming that Dr. Yoganathan were correct that the four-attachment-point valve disclosed in Figure 3 of the '782 patent were inoperable to "repair[] a damaged heart valve," Dr. Yoganathan provides no evidence that it would have required undue experimentation to recognize the desirability of moving from a four-attachment-point valve to a three-attachment-point valve. Instead, Dr. Yoganathan relies on Dr. Snyders' deposition testimony that it took him three to five years to develop a "*right-circular cone*" design and that the method of doing so "is potentially, I think, a trade secret." *See* Ex. 5 at 264:24-268:1 [Snyders Depo]; Ex. 3 at

¹ Indeed, Dr. Snyders' own testimony indicates that he immediately recognized, after he saw the drawings of the four-attachment-point valve from the artist, that the leaflets should have "a dimension which is two radii or one circumference"—*i.e.*, that three leaflets would present the optimal geometry. *See* Ex. 3 at ¶ 134 [Excerpts2—Yoganathan Report]; Ex. 5 at 181:2-3; 182:4-22 [Snyders Depo]. Moreover, the desirability of using three attachment points based on the relationship of the distances between the attachment points to the midline and the circumference of a circle was known in the art, for exactly the reasons Dr. Snyders explained during his deposition. *See, e.g.,* Ex. 6 at 7-8, Fig. 6 [M. Thubrikar, "The Aortic Valve" (CRC Press 1990)].

¶¶ 147-48 [Exerpts2—Yoganathan Report]. Dr. Yoganathan's opinion that it took Dr. Snyders some time after filing to develop an optimized right-circular cone embodiment has nothing to do with the experimentation that one skilled in the art would have required to alter a four-attachment-point valve to a three-attachment-point valve. And Dr. Yoganathan identifies no evidence that the experimentation needed to do the latter would have been undue. *See Koito Mfg. Co.*, 381 F.3d at 1155 ("Koito argues that the '268 patent was not enabled because Turn-Key used a proprietary formula for achieving the claimed predetermined direction of flow . . . and yet did not disclose this formula in the patent. While this evidence may go to best mode, it does not demonstrate that any certain formula for achieving flow direction was required for one of ordinary skill in the art or that undue experimentation would be required for one of ordinary skill in the art to predetermine flow direction through trial and error.").

III. DR. YOGANATHAN'S RELIANCE ON SJM'S INVALIDITY CONTENTIONS

In addition to 236 pages setting forth various opinions on invalidity, Dr. Yoganathan's report attaches SJM's invalidity contentions as Exhibit C and purports to incorporate them by reference. See Ex. 7 at ¶ 234 & Exhibit C [Excerpts3—Yoganathan Report]. The Court should exclude any opinion to which Dr. Yoganathan may seek to testify based on SJM's invalidity contentions alone, as opposed to those opinions that were actually disclosed as required in his report. See, e.g., Changzhou Kaidi Elec. Co., Ltd. v. Okin Am., Inc., 112 F. Supp.3d 330, 339 (D. Md. 2015) (ruling that an expert cannot rely on an incorporation of reference of invalidity contentions to expand beyond the specific opinions disclosed in the expert's report); Promega Corp. v. Applied Biosystems, LLC, Case No. 13-2333, 2013 WL 9988881, *5 (N.D. Ill. May 28, 2013) (same). Reliance on the invalidity contentions would also be improper because they expressly apply an improper "practicing the prior art" approach. See Ex. 7 at ¶ 234 & Exhibit C

[Excerpts—Yoganathan Report]; see also section I above.

IV. DR. YOGANATHAN'S OPINIONS ON UNDISCLOSED THEORIES

Dr. Yoganathan's report includes an "overview" section that expressly asserts that Johnson "is prior art pursuant to 35 U.S.C. § 102(b)" and that specifically maps various portions of Johnson to elements of Dr. Snyders' patent claims. *See* Ex. 8 at ¶¶ 196-201 [Excerpts4—Yoganathan Report]. Additionally, Dr. Yoganathan relies on the combination of Anderson with Johnson in the body of his report. *See id.* at ¶¶ 229, 243, 244, 245, 247, 251.

The Court should exclude these opinions because SJM did not provide a claim chart in its invalidity contentions identifying Johnson as any part of a section 102 or section 103 invalidity theory. Indeed, in opposition to Snyders' motion to strike portions of SJM's invalidity contentions for this reason, SJM admitted that it did not provide a claim chart for Johnson and expressly represented that it was relying on Johnson *only* for section 112 purposes. *See* Dkt. No. 141 at 3-4 ("St. Jude . . . had provided charts for the references it intends to use as 35 U.S.C. § 102 and/or 103 references As to the specific references Snyders objected to . . . these references were cited for other reasons . . . : [Johnson is] discussed as part of St. Jude's *written description section* in its Invalidity Contentions.") (emphasis added).

Dr. Yoganathan also opines that the Hancock porcine valve meets the "u-shaped frame elements" limitation included in some of Dr. Snyders' patent claims. *See* Ex. 8 at ¶ 356 [Excerpts4—Yoganathan Report]. He also relies on the "Freestyle Valve" and an article titled "Porcine Aortic Valves as Replacements for Human Heart Valves" for certain teachings that he opines can be combined with other prior-art references. *See id.* at ¶¶ 388, 404. He also relies on "prior art spokes"—albeit without identifying any specific prior art disclosing spokes. *See id.* at ¶¶ 248-49, 478-79. And he relies on a recently produced publication, "Aortic Regurgitation Due

to Non-traumatic Rupture of the Aortic Valve Commissures," (SJM270465) for its alleged teaching that attachments should be made to a frame as required by Dr. Snyders' patent claims. *See id.* at ¶¶ 480, 486. SJM did not disclose any of this art or any of these theories in its invalidity contentions. The Court should thus exclude these opinions.

V. DR. BROWN'S WRITTEN-DESCRIPTION OPINIONS

The Court should exclude Dr. Brown's opinions on written description because he applies an incorrect legal standard and relies on legally insufficient facts. *See* Section II above.

A patent satisfies the written description requirement when "the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of *the claimed subject matter* as of the filing date." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (emphasis added). The patent must provide a written description for each claim limitation as construed by the Court—and not, it should go without saying, according to constructions expressly rejected by the Court. *See, e.g., Koninklijke Philips Elecs. N.V. v. Cardiac Sci. Operating Co.*, 590 F.3d 1326, 1336 (Fed. Cir. 2010) ("A district court must base its analysis of written description under § 112, ¶ 1 on proper claim construction."). The inventor need only "reasonably convey to one skilled in the art that [the inventor] had possession of at least one embodiment that meets the [proper] construction"

**Tobinick v. Olmarker*, 753 F.3d 1220, 1226-27 (Fed. Cir. 2014). Moreover, absent special genus/species concerns not relevant here, 2 the fact that an original claim included a claim

² The Federal Circuit has questioned whether originally filed claims necessarily satisfy written description in certain contexts (such as when a claim covers a "vast genus of chemical compounds" but the specification does not adequately disclose species sufficient to support such a vast genus). See Ariad, 598 F.3d at 1349. But such concerns do not apply here, where the claims are directed to a mechanical invention and use non-functional language. See Mentor Graphics, 851 F.3d at 1297 ("These claims raise none of the genus/species concerns that have caused us to question whether originally filed claims satisfy written description. . . . The claims

limitation is alone sufficient to satisfy the written description requirement for that limitation. *See, e.g., Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1297 (Fed. Cir. 2017) (reversing ruling that written description was lacking for claim limitations that were in the original claims and thus "part of the original specification").

Dr. Brown has advanced three written description theories. None is legally tenable.

First, Dr. Brown opines that there is not an adequate written description for the "valve element," "flexible valve element," and "flap" claim limitations. See Ex. 6 at 20 [Brown Report]. This theory is meritless because each of these claim limitations appeared in the original claims. See Ex. 4 at SNYDERS 0000081-82 [Prov. App]. Additionally, Dr. Brown admits that Dr. Snyders' patent specifications disclose at least one embodiment of valve element and flap limitations. See, e.g., Ex. 9 at 22-24 [Brown Report]. Despite this, Dr. Brown opines that the written description is not met for these limitations because the specifications do not disclose "a native-type valve with independent leaflets that open outwardly and close inwardly," but instead disclose "only . . . a unitary reversed cusp valve that collapses inwardly to open (to allow blood to flow) and expands outwardly to close (to block blood flow)—which is opposite of a nativetype valve." See id. at 23. The Court, however, expressly rejected SJM's proposal that these claim limitations be limited to unitary, reversed-cusp designs. See Dkt. No. 194 at 47 [10/27/17] *Markman* Order]. Dr. Brown's opinion is thus merely "a round-about attack[] on the claim construction and [Snyders'] infringement allegations rather than an analysis that determines whether the written description supports the claimed invention." Ex. 10 at 11 [Adaptix, Inc. v. Alcatel-Lucent USA, Inc., No. 6:12-cv-22, Dkt. No. 667 (E.D. Tex. Mar. 30, 2016)].

at issue in this case are indistinguishable from other cases relying on originally-filed claims to satisfy the written description requirement.").

Dr. Brown's second theory is flawed in the same way. Dr. Brown opines that there is not an adequate written description for the "frame" limitation because the patents-in-suit do not disclose "a frame other than a conical geodesic birdcage-shaped wire structure." *See* Ex. 9 at 42-43 [Brown Report]. But the "frame" limitation appears in the original claims, which alone satisfies the written description requirement. *See* Ex. 4 at SNYDERS_0000081 [Prov. App]. Indeed, Dr. Brown admits that Dr. Snyders' patent specifications disclose at least one embodiment of a frame. *See*, *e.g.*, Ex. 9 at 43-46 [Brown Report]. And the Court expressly rejected SJM's proposed construction of "frame" requiring it to be a conical geodesic birdcage-shaped wire structure. *See* Dkt. No. 194 at 17 [10/27/17 *Markman* Order].

Dr. Brown's third theory is similarly flawed. Dr. Brown opines that there is not an adequate written description for the limitation requiring the valve element to "be substantially free of connections to the frame except at the central portion of the frame and adjacent the band." See Ex. 9 at 56 [Brown Report]. Although the "substantially free" limitation was not present in the original claims, it was, as Dr. Brown admits, described in the original patent specification, which disclosed an embodiment in which the valve element was connected to the frame at only an apex and at four attachment points adjacent the band. See Ex. 9 at 57 [Brown Report]; Ex. 4 at SNYDERS_000076 [Prov. App]. Despite this, Dr. Brown opines that an adequate written description is lacking because the patents do not disclose "a native-type prosthetic valve with a tubular stent that does not have tissue/material attached to a central structural frame portion that is located at a position on the central axis of the valve but does not have valve tissue material attached all the way around the periphery of the frame or stent." Ex. 9 at 56-57 [Brown Report]. Because the "substantially free" claim limitation requires no such thing, whether such a particular embodiment is disclosed is irrelevant.

VI. CONCLUSION

For the foregoing reasons, the Court should exclude the paragraphs of Dr. Yoganathan's report described above and the entirety of Dr. Brown's report.

Dated: December 12, 2017 Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 12th day of December, 2017, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ Matthew J. Antonelli Matthew J. Antonelli

CERTIFICATE OF CONFERENCE

I hereby certify that I have met the requirements of Local Rule CV-7(h). This motion is opposed. I conferred with counsel for SJM (Alan Heinrich) on December 12, 2017, by telephone. The parties agreed that they were at an impasse on the issues raised by this motion, leaving them open for the Court to resolve.

/s/ Matthew J. Antonelli
Matthew J. Antonelli